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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,206	08/28/2001	Kenton N. Fedde	3376/1 US	5686

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/4

Office Action Summary

Application No.

09/941,206

Applicant(s)

FEDDE ET AL.

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-17 and 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

CLAIMS 1-41 ARE PRESENTED FOR EXAMINATION

Applicant's election with traverse of Group 2, claims 8-17 and 30-41 in the reply filed on May 21, 2004 is acknowledged. The election of species "e" of Group II is also acknowledged, i.e. "the quality of life is improved in a patient suffering from heart disease"

The traversal is on the ground(s) that each of the pending claims is directed to a method of treatment, prevention or improvement comprising the administration of an aldosterone receptor antagonist. Therefore, a search of one restriction group likely will overlap with a search of the other restricted group. The applicants argue that this would not place an undue burden on the examiner.

This is not found persuasive because the etiology of each of the various medical disorders to be treated requires separate considerations and searches especially in the pharmaceutical literature. This will create an undue burden on the examiner. The inventions are also unrelated since they have different effects and have acquired a separate status in the pharmaceutical art.

The requirement is still deemed proper and is therefore made FINAL.

.DETAILED ACTION

Claims 8-17 and 30-41 have been examined only to the extent of the election of Group II (e). That is the compounds have been searched as to their use of improving "the quality of life is improved in a patient suffering from **heart disease**" (Claim 8).

Claims 1-7 and 18-29 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-17 and 30-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (6,410,524 B1).

Perez et al. teach applicants' claimed known compounds, as set forth in claim 31, at column 8, lines 15-31 are administered to treat heart patients at column 18, line 24 to column 26, line 42. The compounds were administered to heart patients, who were given questionnaires to evaluate the quality of life during the treatment with spiro lactone compounds which are aldosterone antagonists. See Column 17, lines 37-39. The quality of their life was also evaluated as to which group showed improvement in an

Art Unit: 1617

NYHA Grouping. See Column 18, lines 26-49. From the results set forth at column 26, lines 19-60 the treatment with spironolactone improved the quality of life of a patient suffering from a heart condition.

The amounts of claimed known compounds to be administered as set forth in claims 38—41 are taught by Perez et al. at column 27, line 65 to column 28, line 10.

The various methods of determining the quality of life, as claimed in claims 9-16, does not lend patentability to claims. Although the applicants claimed agents were not specifically set forth in the studies performed one of ordinary skill in the art would have been motivated to use applicants' known compounds to improve the quality of life in a heart patient with a reasonable degree of expected success.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

None of the claims are allowed.

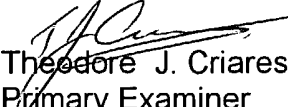
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax

Art Unit: 1617

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Criares
Primary Examiner
Art Unit 1617

8/24/04

tjc